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11/22/02

**AMENDMENT UNDER  
37 C.F.R. §1.116**

Address to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Attorney Docket

LIFE004/LFS097

Confirmation No.

Unassigned

First Named Inventor

Yeung Siu Yu et al.

Application Number

09/497,269

Filing Date

February 2, 2000

Group Art Unit

1634

Examiner Name

B. Forman

Title

*Electrochemical Test Strip  
For Use in Analyte  
Determination*

Sir:

This communication is responsive to the FINAL REJECTION dated August 26, 2002 for which a three-month period for response was given making this response due on or before November 26, 2002. In view of the remarks put forth below, reconsideration and allowance of the pending claims is respectfully requested.

**REMARKS**

Claims 1-14, 16-20, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McAleer et al. in view of Mizutani et al. and Backhaus et al. In maintaining this rejection, the Examiner asserts that it would have been obvious to modify the working electrode of McAleer to include the mercaptopropionic acid of Mizutani, and that it would further have been obvious to modify Mizutani's mercaptopropionic acid to substitute a sulfonate group for the carboxyl group, in view of the teaching of Backhaus, to thereby arrive at the claimed invention.

The Examiner's position appears to be based, at least in part, on the assumption that McAleer discloses "a reaction zone defined by opposing working and reference electrodes separated by a spacer layer wherein at least one of the electrodes has a

surface modified with a homogenous surface modification layer..." Page 2 of the Final Rejection.

However, the structure disclosed in McAleer does not have opposing working and reference electrodes. Instead, the structure disclosed in McAleer is one that has side-by-side working and reference electrodes. Figure 1A of the McAleer patent is an overhead view of the McAleer electrode structure and clearly shows that the working and reference electrodes are not opposing, but side-by-side, in that the faces of the electrodes do not face each other. The Examiner is respectfully requested to acknowledge this fact.

Furthermore, the modification layer disclosed in McAleer is not homogenous. The McAleer modification layer is not homogenous because it is made up of a plurality of different components mixed together. McAleer clearly teaches that the modification layer is made up of a mixture of silica, the glucose oxidizing enzyme and the mediator. See Col. 4, lines 4 to 9. Because McAleer's surface modification layer is made up of several different components, and not a single component, it is not homogenous. The Examiner is respectfully requested to acknowledge this fact as well.

Turning now to the rejection, it is the Examiner's position that it would be obvious to modify McAleer's structure with Mizutani's mercaptopropionic acid. However, the Examiner is silent as to how specifically one would modify McAleer's layer with Mizutani's mercaptopropionic acid. Does the Examiner intend that it would be obvious to substitute Mizutani's mercaptopropionic acid for the silica component of McAleer's surface modification layer? Or does the Examiner intend that it would be obvious to modify McAleer's structure to include a mercaptopropionic acid layer between the electrode surface and the silica containing surface modification layer, i.e., to interpose a mercaptopropionic acid layer between the electrode surface and the silica surface modification layer? The Examiner is respectfully requested to clarify the above position

and, in view of the ambiguity of the rejection because of the above-described uncertainty, withdraw the finality of the August 26, 2002 office action.

Nevertheless, if the Examiner intends that it would be obvious to substitute mercaptopropionic acid for the silica component of the McAleer's surface modification layer, it is respectfully submitted that one of skill in the art would not find such a substitution obvious because there is no indication in any of the combined teachings of the references that such a substitution would result in any kind of workable structure.

McAleer teaches that the silica component of the surface modification layer is chosen so that it forms a two-dimensional honeycomb like structure on the substrate surface which is desirable because, upon rehydration, the material swells to produce a gelled reaction zone that includes the enzymes and mediators. See Col. 4, lines 35 to 40. There is no indication that if one included Mizutani's mercaptopropionic acid in McAleer's modification layer that it would still make the desired two-dimensional structure. There is also no indication that if one included mercaptopropionic acid instead of silica in the surface modification layer, that the desired two-dimensional structure with the desired properties would result. In fact, it is respectfully submitted that including mercaptopropionic acid into the surface modification layer, e.g., instead of the silica, would result in such a different composition that one of skill in the art would not expect it to produce the desired two-dimensional structure. As such, one of skill in the art would not be motivated to modify McAleer's structure with mercaptopropionic acid.

Furthermore, such a structure would not be a homogenous modification layer, since it would include multiple different components. Accordingly, even if one did modify McAleer according to this first proposed way, such a combination would not meet all of the limitations of the claimed invention, required a homogenous surface modification layer made up of a single component.

If the Examiner intends that it would be obvious to modify McAleer's structure by including a layer of mercaptopropionic acid between the silica modification layer and the electrode surface, it is respectfully submitted that, for the following reasons, one would not actually be motivated to make such a modification to McAleer.

This motivation would actually not be present because, as described above, McAleer discloses a surface modification layer made up of molecules that interact with the surface properties of the electrode surface to produce the desired two-dimensional honeycomb structure. If one interposed a layer of mercaptopropionic acid between the silica modification layer and the electrode surface, the desired two-dimensional structure would not form because the surface properties of the electrode would be completely masked, and the silica layer would form a different structure. Accordingly, one of skill in the art would not actually be motivated to modify McAleer to include the mercaptopropionic acid layer between the electrode surface and the silica surface modification layer because to do so would likely destroy the possibility that the desired two-dimensional structure would form on the electrode surface.

As shown above, whatever modification the Examiner intends in making this rejection, i.e., either putting the mercaptopropionic acid into the surface modification layer or interposing it between the electrode surface and the surface modification layer, one of skill in the art would not actually be motivated to make such a modification, for the reasons provided above.

Since Backhaus has been cited solely for the proposition that it would be obvious to substitute a sulfonate moiety for the carboxylic acid moiety in mercaptopropionic acid, this reference fails to provide any motivation for one to modify McAleer's structure with mercaptopropionic acid, whether or not this acid component is modified to include the sulfonate moiety.

For the reasons stated above, the skilled artisan would not be motivated to combine McAleer et al, Mizutani et al., and Backhaus et al. to arrive at the instant invention, because inclusion of mercaptoprionic acid into the McAleer structure would not be expected to maintain the benefits sought after by McAleer, i.e., to preserve the two-dimensional structure on the surface. Accordingly, this rejection of Claims 1-14, 16-20, 26, and 27 under 35 U.S.C. §103(a) may be withdrawn.

Claim 15 has been rejected under 35 U.S.C. §103(a) as being unpatentable over McAleer et al. in view of Mizutani et al., Backhaus et al., and Pritchard et al. The Office asserts that it would have been obvious to one skilled in the art to apply the palladium electrode of Pritchard et al. to the electrodes of McAleer et al. and Mizutani et al.

The deficiencies of McAleer et al., Mizutani et al., and Backhaus et al. are described above. Pritchard et al. does nothing to remedy the deficiencies of the previously cited references. First, the test strip of Pritchard et al. does not have opposing electrodes because Pritchard discloses a side-by-side or coplanar configuration. Second, Pritchard et al. simply states that palladium can be used to make an electrode of an electrochemical test strip.

Thus, Pritchard et al. provides no motivation to the skilled artisan to combine the cited references, nor a reasonable expectation of arriving at the instant invention if the references were combined, as discussed above for the rejection of Claims 1-14, 16-20, 26, and 27. Finally, Pritchard et al. fails to provide a test strip having opposing electrodes. Accordingly, this rejection of claim 15 under 35 U.S.C. §103(a) should be withdrawn.

### **Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite

the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE004.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 11.22.02

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